

U.S. PATENT APPLICATION
SERIAL NO.:
PRELIMINARY AMENDMENT

ATTY DOCK: 3968.088

REMARKS

Applicants have elected to prosecute process claims of their invention. The reasons that the process claims are believed to be patentable are detailed below.

Support for the amendment to the specification, paragraph [00054] can be found in claim 7, as originally filed. Care has been taken to ensure that no new matter has been entered.

Claims 1-16 are cancelled. Claims 17-24 have been added.

Support for the new claims can be found, *inter alia*, in paragraphs 16, 25, 26, 30, 67, 70 and 72 of the specification, as originally filed. Claims 17-24 are currently pending in the application.

The Invention

Physiological cooling agents are known. These agents generally fall into two categories. The first category of agents, such as those disclosed by Hanke et al., have no taste and are characterized by the creation of a cooling sensation on the mucous membrane in which they come into actual contact. The second category of agents can generally be referred to as menthols. The cooling sensation of menthols is not localized, but menthols have a bitter and distinctive taste that reduces their desirability.

Applicants thought that there might be a need for a compound with nasal cooling and no taste, but, given the state of the art, they were unable to find any teaching on how to select those desired compounds. They hypothesized that compounds with a low volatility could achieve this preferred effect. After much experimentation and testing of many compounds, it was discovered that certain compounds, when taken orally, would allow the cooling feeling to spread from the mouth into all areas of the airways. In conclusion, this invention was not obvious, because, in the absence of teaching by Hanke that certain compounds could be selected which were volatile and would spread to the nasal and pharyngeal cavities, there was no reason why Applicants should select from the long list of compounds disclosed in Hanke, those compounds that would always create nasal cooling when administered to a subject orally.

Anticipation

In the parent case, the Examiner cited several prior art references as anticipating the composition claims of the parent invention. The claims now presented are believed to fully distinguish over the teachings of these references. The composition claims have been amended to claim a process that provides a clearing feeling in the nasal and pharyngeal cavities. None of the prior art references contain any teaching of the clearing feeling that is currently claimed in the application. Thus, Applicants respectfully assert that the new

claims are not anticipated by the prior art.

Obviousness- Hanke et al.

In the parent case, the Examiner cited Hanke et al. as rendering the composition claims of the parent invention obvious.

In Ex parte Viscardi, the applicant discovered that the addition of carbon dioxide would completely remove static electricity. The Examiner rejected the application over a reference that taught the addition of carbon dioxide, but for a different reason. The issue was whether the addition of carbon dioxide to completely remove static electricity was novel. The court held that the invention was unobvious. The rule of law is that a significant and unobvious improvement could be used to rebut an obviousness rejection. The court reasoned that in the absence of appreciation by the patentee of the fact that carbon dioxide will completely remove a charge of static electricity, there was no reason why the inventor, or one skilled in the art following the patentee's teaching, should inherently adjust the concentration of carbon dioxide for the removal of the complete static charge.

Similarly, the present inventors discovered that the selection of certain volatile compounds could produce a clearing/cooling feeling in the nasal and pharyngeal cavities without an unpleasant taste. Hanke et al., as cited by Examiner, does not teach that such properties of the

compositions exist. Hanke reveals that a cooling feeling can be created in the limited region of the mucous membrane where actual contact occurs. However, Hanke also discloses a laundry list of compounds which could achieve this effect. Only after much experimentation and testing of many compounds did the present Applicants discover that certain compounds disclosed in the long list of compounds in Hanke could create that cooling feeling. Thus, in the absence of teaching by Hanke that these compounds were volatile and would spread to the nasal and pharyngeal cavities, there was no reason why Applicants, or one skilled in the art following Hanke's teaching, should select from the list disclosed by Hanke, those compounds that would always create nasal cooling when administered to a subject orally.

As discussed on page 4, lines 3-5 of the specification, the present invention causes a refreshing clearing feeling in the pharyngeal cavity and the airways, i.e. the nasal cavity. Additional support can be found on page 5, lines 6-7 of the specification. Further, quantitative experiments tested under conditions of practice by an expert panel trained in sensory testing support the description of the refreshing clearing feeling created by the rhinologically active substances in the pharyngeal cavity and the airways, i.e. the nasal cavity. (see Examples 2-4 on pages 14-16). The expert panel's conclusions were that a pronounced markedly refreshing, clearing feeling

could be perceived in the airways and in the **pharyngeal cavity**. This effect was new and surprising.

Hanke does not teach the possibility that its composition can create a feeling in an area of the body that the composition does not come into **actual** contact with. Hanke does not disclose any property of the cooling agents that includes the ability to provide a cooling-refreshing and clearing feeling in the throat, pharyngeal cavity, nasal cavity, and airways (areas that the composition, placed in the mouth, would come into contact with). As taught by Hanke, the known properties of the described compounds have the desired effect only on/in the mucous membrane of the mouth where **actual contact** is made between the composition and the tongue (see column 3, lines 40-42).

Surprisingly, the present invention is able to produce a clearing and cooling sensation in the nasal cavity and pharyngeal cavity, even though the present invention **never actually comes in contact** with these regions. A person using the rhinologically active substances of the present invention experiences the sensation of "nasal cooling," even though the composition never comes into direct contact with the nasal region.

Third, the use of the rhinologically active substances found in the present invention is not accompanied by a strong and unpleasant taste (see specification page 1, lines 19-24). As it is currently known in the art, a clearing feeling can be created in the nasal and pharyngeal cavities by menthol, for

example. Unfortunately, menthol produces an unpleasant (bitter) taste if present in too large of a quantity, and menthol has a distinctive taste (mint) even in smaller quantities. Thus, the prior art teaches that a clearing feeling can only be associated with an unpleasant taste.

The compounds of Hanke are not associated with any unpleasant tastes, but the problem with the properties of the Hanke compositions is that the cooling feeling does not extend to the nose or pharyngeal cavity. Thus, the prior art does not teach that it is possible to create clearing/cooling agents without also experiencing a strong and unpleasant typical taste (see specification page 1, lines 20-24).

Therefore, there was a need for a composition that could provide a clearing feeling in the nasal or pharyngeal cavities and that had a pleasant taste (or no taste at all). Surprisingly, the present invention is able to provide a clearing feeling in the nasal or pharyngeal cavities, and it also has a **pleasant, refreshing taste property**.

In contrast to the Hanke compounds and to menthol, the compounds of the present invention have the unique ability to provide a sensation of freshness and clearing/cooling while at the same time exhibiting a fresh, ethereal, minty, cooling, sweet, and fruity flavor notes (see specification page 3, lines 7-10). Therefore, the present invention is also outstandingly suitable for use as a flavor compound (see specification page 3, lines 7-10). The compounds of the present invention can even be

considered as volatile flavor compounds rather than only as physiologically cooling substances.

Additionally, the compounds of the present invention are able to enhance the effect of freshness produced by other aroma compounds, and they are able to harmonically combine the sensation of freshness with aroma of very different tastes to form a harmonic total aroma (see page 5, lines 5-10). This effect was new and unexpected.

An additional distinction of the present rhinologically active substances is found on page 9, lines 9-13. It was unpredictably found that the strong medicinal flavor note of eucalyptol can be reduced without reducing the refreshing clearing feeling in the pharyngeal cavity and the airways.

Another surprising property of the present invention is that the perception of freshness is of longer duration than that caused by eucalyptol (see specification page 9, lines 13-16).

In conclusion, the present invention's rhinologically active substance produce both a refreshing clearing feeling in the pharyngeal cavity and the airways, i.e. the nasal cavity. Further, this feeling is produced without any actual contact between the compositions and these areas of the body. Finally, the compositions exhibit a mild and pleasant flavor.

In conclusion, Applicants believe that Hanke et al. has not taught the current process claims.

Obviousness- Conrad et al.

In the parent case, the Examiner cited Conrad et al. as rendering the composition claims of the parent invention unpatentable.

Conrad et al. teaches a composition. Conrad does not teach a process for providing a clearing feeling. Further, Conrad does not teach that its compositions are capable of creating a clearing feeling in the nasal and pharyngeal cavities. The only mention of the properties of the chemical compositions taught in Conrad refers to a perfumery composition having natural and pleasing fragrances. (See column 1, lines 2-3). One would not expect the pleasing perfume taught by Conrad to be capable of producing a clearing feeling in the nasal and pharyngeal cavities.

Applicants believe that the current process claims are not obvious with respect to Conrad et al.

Obviousness- Thomas et al.

In the parent case, the Examiner cited Thomas et al. as rendering the composition claims of the parent invention unpatentable. Thomas et al. does include process claims, but they are not directed toward the ability to create a clearing refreshing feeling.

Thomas et al. does not teach the process for providing a clearing feeling. Further, Thomas does not teach that its compositions are capable of creating a clearing feeling in the

U.S. PATENT APPLICATION
SERIAL NO.:
PRELIMINARY AMENDMENT

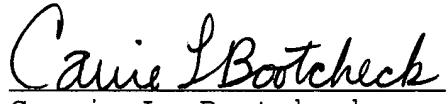
ATTY DOCK: 3968.088

nasal and pharyngeal cavities. The properties of the chemical compositions taught in Thomas refer to a "flowery, fruity, green, spicy, woody or even slightly animal notes (see column 3, lines 2-6. See also Examples 8 and 9 for further description of the flowery and fruity description of the perfumed composition). One would not expect the flowery and fruity perfume taught by Thomas to be capable of producing a clearing feeling in the nasal and pharyngeal cavities.

Applicants believe that the current process claims are not obvious with respect to Thomas et al.

It is respectfully submitted that all claims are allowable. Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,



Carrie L. Bootcheck
Reg. No. 50,712

Pendorf & Cutliff
5111 Memorial Highway
Tampa, Florida 33634-7356
(813) 886-6085

Dated: July 24, 2003